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FEE TRANSMITTAL		Complete if Known	
Patent fees are subject to annual revision.		Application Number	10/042,761
		Filing Date	January 15, 2003
		First Named Inventor	A.G. Daifotis et al.
		Examiner Name	To be determined
		Group Art Unit	To be determined
		Attorney Docket Number	20002YPCI
TOTAL AMOUNT OF PAYMENT		\$180	

METHOD OF PAYMENT (Check one)		FEE CALCULATION (continued)																																																																																																					
<input checked="" type="checkbox"/> Deposit Account Deposit Account Number: 13-2755 Deposit Account Name: Merck & Co., Inc. The Director is authorized to: <input checked="" type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments <input checked="" type="checkbox"/> Charge any additional fee(s) during the pendency of this application		3. ADDITIONAL FEES <table border="1"><thead><tr><th>Fee Code</th><th>Large Entity Fee (\$)</th><th>Fee Description</th><th>Fee Paid</th></tr></thead><tbody><tr><td>1051</td><td>130</td><td>Surcharge - late filing fee or oath</td><td></td></tr><tr><td>1812</td><td>2,520</td><td>For filing a request for <i>ex parte</i> reexamination</td><td></td></tr><tr><td>1251</td><td>110</td><td>Extension for reply within first month</td><td></td></tr><tr><td>1252</td><td>410</td><td>Extension for reply within second month</td><td></td></tr><tr><td>1253</td><td>930</td><td>Extension for reply within third month</td><td></td></tr><tr><td>1254</td><td>1,450</td><td>Extension for reply within fourth month</td><td></td></tr><tr><td>1255</td><td>1,970</td><td>Extension for reply within fifth month</td><td></td></tr><tr><td>1401</td><td>320</td><td>Notice of Appeal</td><td></td></tr><tr><td>1402</td><td>320</td><td>Filing a brief in support of an appeal</td><td></td></tr><tr><td>1403</td><td>280</td><td>Request for oral hearing</td><td></td></tr><tr><td>1452</td><td>110</td><td>Petition to revive - unavoidable</td><td></td></tr><tr><td>1453</td><td>1,300</td><td>Petition to revive - unintentional</td><td></td></tr><tr><td>1501</td><td>1,300</td><td>Utility issue fee (or reissue)</td><td></td></tr><tr><td>1502</td><td>470</td><td>Design issue fee</td><td></td></tr><tr><td>1460</td><td>130</td><td>Petitions to the Commissioner</td><td></td></tr><tr><td>1807</td><td>50</td><td>Processing fee under 37 CFR 1.17(q)</td><td></td></tr><tr><td>1806</td><td>180</td><td>Submission of Information Disclosure Statement</td><td>180</td></tr><tr><td>8021</td><td>40</td><td>Recording each patent assignment per property (times number of properties)</td><td></td></tr><tr><td>1809</td><td>750</td><td>Filing a submission after final rejection (37 CFR 1.129(a))</td><td></td></tr><tr><td>1810</td><td>750</td><td>For each additional invention to be examined (37 CFR 1.129(b))</td><td></td></tr><tr><td>1801</td><td>750</td><td>Request for Continued Examination (RCE)</td><td></td></tr><tr><td colspan="3">Other fee (specify) _____</td><td></td></tr><tr><td colspan="3">Other fee (specify) _____</td><td></td></tr><tr><td colspan="3">SUBTOTAL(3)</td><td>\$180</td></tr></tbody></table>		Fee Code	Large Entity Fee (\$)	Fee Description	Fee Paid	1051	130	Surcharge - late filing fee or oath		1812	2,520	For filing a request for <i>ex parte</i> reexamination		1251	110	Extension for reply within first month		1252	410	Extension for reply within second month		1253	930	Extension for reply within third month		1254	1,450	Extension for reply within fourth month		1255	1,970	Extension for reply within fifth month		1401	320	Notice of Appeal		1402	320	Filing a brief in support of an appeal		1403	280	Request for oral hearing		1452	110	Petition to revive - unavoidable		1453	1,300	Petition to revive - unintentional		1501	1,300	Utility issue fee (or reissue)		1502	470	Design issue fee		1460	130	Petitions to the Commissioner		1807	50	Processing fee under 37 CFR 1.17(q)		1806	180	Submission of Information Disclosure Statement	180	8021	40	Recording each patent assignment per property (times number of properties)		1809	750	Filing a submission after final rejection (37 CFR 1.129(a))		1810	750	For each additional invention to be examined (37 CFR 1.129(b))		1801	750	Request for Continued Examination (RCE)		Other fee (specify) _____				Other fee (specify) _____				SUBTOTAL(3)			\$180
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SUBMITTED BY			Complete (if applicable)	
Typed or Printed Name	J. Antonio Garcia-Rivas		Reg. Number	42,567
Signature		Date	8/14/03	Deposit Account User ID

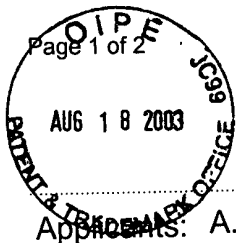
Application Number: 10/042,761
Filing Date: 01/15/2003
First Named Inventor: A.G. Daifotis et al.
Group Art Unit: To be determined
Examiner Name: To be determined
Attorney Docket Number: 20002YPCI

FIRST CLASS MAIL CERTIFICATE

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450, ON THE DATE APPEARING BELOW.

MERCK & CO., INC.

MAILED BY Barbara Muller DATE 8-14-03



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: A.G. DAIFOTIS et al.

Serial No. 10/042,761

Filed: January 15, 2003

For: METHOD FOR INHIBITING BONE
RESORPTION

Art Unit: To be determined

Examiner: To be determined

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application.

This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

08/20/2003 JADD01 00000051 132755 10042761
01 FC:1806 180.00 DA

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Barbara Muller Date 8-14-03

**INFORMATION DISCLOSURE STATEMENT**

4. Except for Cite Nos. 96-116, copies of the references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE
09/376,315	August 18, 1999	20002YPCB

upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.

5. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,


By: J. Antonio Garcia-Rivas

Attorney _____ For Applicant(s)

Reg. No. 42,567

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-1513

Date: August 14, 2003



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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of

8

COMPLETE IF KNOWN

Application Number	10/042,761
Filing Date	January 15, 2003
First Named Inventor	A.G. Daifotis
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Examiner Name	To be determined
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	1	5,270,365		Gertz et al.	12/14/1993
	2	5,366,965		Strein	11/22/1994
	3	4,761,406		Flora et al.	08/02/1988
	4	4,425,339		Pitchford	01/10/1984
	5	4,621,077		Rosini et al.	11/04/1986
	22	5,616,560		Geddes	04/01/1997
	23	5,780,455		Brenner et al.	07/14/1998
	24	5,773,429		Fuisz	06/30/1998
	27	5,488,041		Barbier et al.	01/30/1996
	28	4,980,171		Fels et al.	12/15/1990
	40	4,812,304		Anderson et al.	03/14/1989
	41	4,822,609		Flora	04/18/1989
	48	5,358,941		Bechard et al.	10/25/1994
	49	5,616,571		Daifotis et al.	04/01/1997
	50	5,853,759		Katdare et al.	12/29/1998
	51	5,804,570		Santora II et al.	09/08/1998
	58	5,583,122		Benedict et al.	12/10/1996
	59	5,622,721		Dansereau et al.	04/22/1997
	60	4,927,814		Gall et al.	05/22/1990
	63	5,994,329		Daifotis et al.	11/30/1999

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	6		WO 95/30421		Goodship et al.	11/16/1995
	7		WO 96/17616		Gazard	06/13/1996
	8		WO 94/00129		Francis et al.	01/06/1994
	9		WO 94/00130		Hovancik et al.	01/06/1994
	10		WO 94/21242		D'Souza et al.	09/29/1994
	25		WO 95/28145		Shinoda et al.	10/26/1995
	26		EP 0 600 834 A1		Goodship et al.	08/06/1994
	37		EP 0 274 158		Ebetino et al.	07/13/1988
	38		WO 95/08331		Bechard	03/30/1995
	39		WO 95/28936		Yates	11/02/1999

Examiner
SignatureDate
Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	11	Lunar News, April 1997, "Update: Bisphosphonate", pp. 30-32
	12	Gertz et al., Osteoporosis Int. (1993), Suppl. 3: S13-16, "Clinical pharmacology of alendronate sodium"
	13	Gertz et al., Clin. Pharma. Ther. (1995), Vol. 58, pp. 288-98, "Studies of the oral bioavailability of alendronate"
	14	de Vernejoul et al., Calcified Tissue Int'l, Vol. 40 (1987), pp. 160-165, "Different schedules of administration of (3 amino-1-hydroxypropylidene)-1,1-bisphosphonate induce different changes ..."
	15	Lufkin et al., Osteoporosis Int'l. (1994), Vol. 4, pp. 320-322, "Pamidronate: An unrecognized problem in gastrointestinal tolerability".
	16	De Groen et al., N. England J. of Medicine, (1996), Vol. 335, pp. 1016-1021, "Esophagitis associated with the use of alendronate"
	17	Castell, (an editorial), N. England J. of Medicine (1996), Vol. 335, pp. 1058-1059, "Pill esophagitis - the case of alendronate".
	18	Liberman et al., (correspondence), N. England J. of Medicine (1996), Vol. 335, pp. 1069-1070, "Esophagitis and alendronate".
	19	Chesnut et al., Am. J. of Medicine, Vol. 99 (1995), pp. 144-152, "Alendronate treatment of the postmenopausal osteoporotic woman ...".
	20	Cassidy et al., Digestive Diseases and Sciences, Vol. 37 (1992), pp. 1206-1211, "Continuous versus intermittent acid exposure in production of esophagitis in feline model".
	21	Mortensen et al., J. of Bone & Mineral Res., (1995) Vol. 10, suppl. 1, p. s140, "Prevention of early postmenopausal bone loss of risendronate".
	29	Singer et al., Advances in Endocrin.& Metab., Vol. 6 (1995), pp. 259-288, "Bisphosphonates in the treatment of disorders or mineral metabolism".
	30	Lieberman et al., N. Eng. J. of Medicine, Vol. 333 (1995), pp. 1437-1443, "Effect of oral alendronate on bone mineral density and the incidence of fractures in postmenopausal osteoporosis".
	31	Bankhurst et al., Arthritis and Rheumatism, Vol. 38, No. 9, Suppl. 1 (1995), S359, "Three-year treatment with alendronate prevents fractures in women with postmenopausal osteoporosis".
	32	Filipponi et al., J. of Bone & Min. Research, Vol. 10 (1995), pp. 697-703, "Cyclical clondronate is effective in preventing postmenopausal bone loss: A comparative study with transcutaneous hormone replacement therapy".

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OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	33	McClung et al., Bone, Vol. 17 (1995), pp. 493S-496S, "Tiludronate therapy for Paget's disease of bone".
	34	Seltenmeyer et al., Bone (NY), Vol. 20, No. 4, Suppl., (1997) pp. 114S, "A comparison of the antiresorptive potency of various bisphosphonates in vivo with their inhibitory effect in vitro on squalene synthase and cellular sterol synthesis".
	35	Adachi et al., Today's Therapeutic Trends, Vol. 14, No. 1 (1996), pp. 13-24, "Osteoporosis -- its diagnosis, management and treatment with a new oral bisphosphonate agent, etidronate".
	36	Bell et al., Endocrine, Vol. 6(2) (1997), pp. 203-206, "Bisphosphonates in the Treatment of Osteoporosis".
	42	Melsen et al., Osteoporosis, Chapt. 60(1996), pp. 1145-1158, "ADFR - The Concept and its performance".
	43	Thompson et al., J. of Bone & Min. Research, Vol. 7(1992), pp. 951-960, "The bisphosphonate, alendronate, prevents bone loss in ovariectomized baboons".
	44	Balena et al., J. Clin. Invest., Vol. 92 (1993), pp. 2577-2586, "The effects of 2-year treatment with the aminobisphosphonate alendronate on bone metabolism, bone histomorphometry, and bone strength in ovariectomized nonhuman primates".
	45	Peter et al., Digestive Diseases & Sciences, Vol. 43 (1998), pp. 1009-1015, "Comparative study of potential for bisphosphonates to damage gastric mucosa of rats".
	46	Peter et al., Digestive Diseases & Sciences, Vol. 43 (1998), pp. 1998-2002, "Esophageal irritation due to alendronate sodium tablets".
	47	Harris et al., J. of Clin. Endoc. & Metab., 76:1399-1406 (1993), "The effect of short term treatment with alendronate on vertebral density and biochemical markers of bone...".
	52	Khan et al., Bone, Vol. 20 (1997), pp. 263-271, "Alendronate in the treatment of Paget's disease of bone".
	53	Physician's Desk Reference, 51st ed. (1997), pp. 1703-1706, "Fosamax".
	54	Gertz et al., J. of Bone & Min. Res., Vol. 9 (1994), pp 135-142, "Monitoring bone resorption in early postmenopausal women by an immunoassay for cross-linked collagen peptides in urine".
	55	Fleisch, J. of Clin. Endoc. & Metab., Vol. 76 (1993), pp. 1397-1398, "Editorial: Prospective use of bisphosphonates in osteoporosis".
	56	Chesnut et al., Osteoporosis Int'l (1993), Suppl. 3: S17-19, "Short-term effect of alendronate on bone mass and bone remodeling in postmenopausal women".

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Attorney Docket Number	20002YPCI

Sheet 5 of 8

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

COMPLETE IF KNOWN

Application Number	10/042,761
Filing Date	January 15, 2003
First Named Inventor	A.G. Daifotis
Group Art Unit	To be determined
Examiner Name	To be determined
Attorney Docket Number	20002YPCI

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of

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Sheet	7	of	8	Attorney Docket Number	20002YPCI

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